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APPLICATION NUMBER: 60/547,483

FILING DATE: *February 25, 2004*

RELATED PCT APPLICATION NUMBER: PCT/US05/05782



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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 C.F.R. 1.53 (c).

Docket Number	230.00090160	Type a plus sign (+) inside this box >	+ 22154 U.S. PTO 60/547483
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INVENTOR(s)/APPLICANT(s)			
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RAJAN, Elizabeth GOSTOUT, Christopher J. BENNET, Kevin E.		Rochester, MN Rochester, MN Rochester, MN	
TITLE OF THE INVENTION (280 characters max)			
GASTRIC BYPASS DEVICES AND METHODS			
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STATE	Minnesota	ZIP CODE	55458-1415
COUNTRY	United States of America		
ENCLOSED APPLICATION PARTS (check all that apply)			
<input checked="" type="checkbox"/> /	Specification	Number of Pages	<u>13</u>
<input checked="" type="checkbox"/>	Drawing(s)	Number of Sheets	<u>4</u>
			<input checked="" type="checkbox"/> Small Entity Statement
			<input checked="" type="checkbox"/> Other (specify) <u>Application Data Sheet (2 pgs)</u>
METHOD OF PAYMENT (check one)			
<input checked="" type="checkbox"/>	A check or money order is enclosed to cover the Provisional filing fees		PROVISIONAL FILING FEE AMOUNT
<input checked="" type="checkbox"/>	The Commissioner is hereby authorized to charge any additional required fees or credit overpayment to Deposit Account Number: <u>13-4895</u>		
			(\$) <u>160</u>

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government:

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE *Kevin W. Raasch*

Date FEBRUARY 25, 2004

TYPED OR PRINTED NAME Kevin W. Raasch

REGISTRATION NO. 35,651

☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

Exp. Mail No. EV 405458496 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rajan et al.

Docket No.: 230.00090160

Title: GASTRIC BYPASS DEVICES AND METHODS

Assistant Commissioner for Patents

ATTN: MAIL STOP PROVISIONAL PATENT APPLICATION

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We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

☒ PROVISIONAL PATENT APPLICATION including:

☒ Specification (13 consecutively numbered pgs, including 2 claims);

☒ Drawings (4 sheets);

☐ Photographs (sheets);

☒ Provisional Application Cover Sheet (1 pg).

☒ A check in the amount of \$160 to pay the provisional application filing fee.

☐ Verified statement(s) establishing small entity status of this application under 37 C.F.R. 1.9 and 1.27 is/are enclosed.

☒ An itemized return postcard.

☐ An Assignment of the invention to and Recordation Form Cover Sheet (pgs).

☐ A check in the amount of \$40.00 to cover the Assignment Recording Fee.

☐ Computer readable form of "Sequence Listing." Applicants state that the paper copy form of the "Sequence Listing" section of the present application, and the computer readable form submitted herewith, are the same.

☒ Other: Application Data Sheet (2 pgs).

Please consider this a **PETITION FOR EXTENSION OF TIME** for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. A triplicate copy of this sheet is enclosed.

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CERTIFICATE UNDER 37 CFR §1.10:

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By: 

Name: SAM HEA

(PROVISIONAL TRANSMITTAL UNDER RULE 1.10)

5 GASTRIC BYPASS DEVICES AND METHODS

The present invention relates to the field of devices and methods for weight control.

10 A variety of medical approaches may be used to achieve weight loss or control in humans and/or animals. The approaches may include exercise, diets, medication, surgical procedures, etc. and combinations of two or more different approaches. Surgical procedures may include, e.g., removing part of the stomach and rearranging the small bowel, stapling part of the stomach and rearranging the small bowel, bypassing the stomach by rearranging the jejunum and making a pouch of the upper intestines.

15 Such procedures are, however, irreversible and may cause the patient to experience symptoms such as, e.g., indigestion, poor vitamin uptake, diarrhea, malnutrition, etc. In addition, these procedures necessarily involve some inherent risk to the patient as surgical procedures. In spite of these disadvantages, patients still proceed with the surgical approaches when faced with the need to achieve weight loss
20 to address obesity.

SUMMARY OF THE INVENTION

The present invention provides devices and methods for achieving weight loss in obese and morbidly obese patients. The invention combines a gastric bypass (in which
25 ingested food bypasses the stomach and, preferably, the proximal small bowel) and a satiety device in the form of one or more expandable chambers, that tend to induce a feeling of satiety after the patient has consumed a relatively small amount of food.

This combination of gastric bypass and satiety structure can provide significant advantages in achieving weight loss using a device that can preferably be delivered and
30 removed using minimally invasive procedures such as an endoscope. In some instances, the gastric bypass device itself can form the satiety structure and in other

devices, the gastric bypass may be independent of the satiety structure (which may be provided as one or more expandable chambers).

In at least some embodiments, it may be preferred that the gastric bypass and/or expandable chambers of the devices be somewhat permeable to gastric fluids or allow for their removal from the stomach. If gastric fluids are permitted to enter the gastric bypass, motility of ingested food therethrough may be enhanced. Other potential advantages of providing for the removal or drainage of at least some gastric fluids may include, e.g., reducing the likelihood of bezoars, etc.

On the esophageal side, it may be preferred that the device be attached securely to the esophagus to guide ingested food into the gastric bypass. Examples of such attachments may include one or more techniques, e.g., endoscopic suturing, stapling, creating an outward flaring of the esophageal tube similar to that found in, e.g., enteral stents, etc.

On the duodenal side, it may be preferred that the devices of the present invention prevent or reduce contact between ingested food and the duodenal passage such that the absorption of nutrients from the ingested food can be reduced. In some instances, the devices may include a duodenal extension that extends from the pyloric sphincter to the jejunum.

In one aspect, the present invention provides an implantable gastro-intestinal device including a gastric bypass having an inlet and an outlet; an expandable chamber attached to the gastric bypass; an esophageal extension attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; and a duodenal extension attached to the outlet of the gastric bypass, wherein the duodenal extension receives material exiting the outlet of the gastric bypass.

In another aspect, the present invention provides an implantable gastrointestinal device including a gastric bypass having an inlet and an outlet; an expandable chamber attached to an outer surface of the gastric bypass, wherein the expandable chamber comprises a plurality of adjacent subchambers in fluid communication with each other, wherein the plurality of adjacent subchambers are distributed over at least a portion of the outer surface of the gastric bypass, and wherein the plurality of adjacent subchambers maintain an open volume in the gastric bypass in the absence of

compressive forces thereon; an esophageal extension attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; and a duodenal extension attached to the outlet of the gastric bypass, wherein the duodenal extension receives material exiting the outlet of the gastric bypass.

5 In another aspect, the present invention provides an implantable gastro-intestinal device including a gastric bypass having an inlet and an outlet; an expandable toroidal chamber located proximate the inlet of the gastric bypass, wherein the toroidal chamber holds the inlet in an open configuration when the toroidal chamber is inflated; an esophageal extension attached to the inlet of the gastric bypass, wherein food passes
10 into the gastric bypass through the esophageal extension; and a duodenal extension attached to the outlet of the gastric bypass, wherein the duodenal extension receives material exiting the outlet of the gastric bypass.

These and other features and advantages of the present invention may be described below in connection with various exemplary embodiments of the devices and
15 methods of the present invention.

BRIEF DESCRIPTIONS OF THE FIGURES

FIG. 1A depicts one exemplary embodiment of one device according to the present invention in location within the gastrointestinal system of a patient.

20 FIG. 1B is a cross-sectional view of the device of FIG. 1A, taken along a plane parallel to the paper on which FIG. 1A appears.

FIG. 1C is a perspective view of the device of FIGS. 1A & 1B.

FIG. 2 is a cross-sectional view of another exemplary embodiment of a device according to the present invention.

25 FIG. 3 is a partial cross-sectional view of a portion of another exemplary embodiment of a device according to the present invention.

FIG. 4 depicts an alternative exemplary embodiment of a device according to the present invention.

FIG. 5 is an enlarged cross-sectional view of a portion of the device of FIG. 4.

30 FIG. 6 depicts another alternative embodiment of the present invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS OF THE
PRESENT INVENTION

In the following detailed description of some exemplary embodiments of the invention, reference is made to the accompanying figures of the drawing which form a
5 part hereof, and in which are shown, by way of illustration, specific embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

FIGS. 1A-1C depict a device according to the present invention in position in
10 the gastrointestinal system of a patient. The device includes a gastric bypass 10 that includes an inlet 12 located proximate the esophagus and an outlet 14 located proximate the pyloric valve at the exit of the stomach and entrance to the duodenum. The device may preferably include one or more flaps 16 or other structures to prevent or reduce the likelihood of food re-entering the esophagus after passing into the gastric bypass 10.

15 The gastric bypass 10 may preferably be provided in the form of a gastric bag that is flexible such that normal movement of the stomach can compress and distort the gastric bag to improve the motility of ingested fluid therethrough. In some instances, it may be preferred that the gastric bypass 10 be in the form of a flaccid gastric bag, i.e., a flexible bag that has no self-supporting shape. It may also be preferred that the gastric
20 bypass 10 exhibit some permeability to gastric fluids which may, e.g., improve the motility of ingested food, reduce the likelihood of bezoar formation in the stomach, etc.

The device also preferably includes an esophageal extension 20 attached to the inlet 12 of the gastric bypass 10. Food ingested by a patient preferably passes into the gastric bypass 10 through the esophageal extension 20. In addition to directing ingested
25 food into the gastric bypass 10, the esophageal extension 20 may also serve to anchor or fix the gastric bypass 10 in position relative to the esophagus. The esophageal extension 20 may also provide a location at which the device can be attached or fixed to the patient using, e.g., sutures, staples, etc.

A duodenal extension 30 is depicted in connection with the device, with the
30 duodenal extension 30 attached to the outlet 14 of the gastric bypass 10. The duodenal extension 30 preferably receives material exiting the outlet 14 of the gastric bypass 10

and may also preferably prevent or at least reduce contact between that food and the proximal small bowel. By reducing contact between ingested food and the small bowel, the amount of nutrition that can be obtained from the ingested food can be reduced.

- The duodenal extension 30 terminates at an end 32 that may preferably be located in the jejunum. It may also be preferred that the duodenal extension exhibit some permeability to duodenal juices that may, e.g., improve the motility of ingested food, reduce the likelihood of obstruction in the duodenal extension, etc.

- The device depicted in FIGS. 1A-1C may also preferably include an expandable chamber 40 in the form of a toroid. The toroidal chamber 40 includes a volume 42 when inflated. The toroidal chamber 40 may serve one or more different functions in connection with the device. For example, the expanded chamber 40 may preferably hold the inlet 12 of the gastric bypass 10 open when expanded. By so doing, the chamber 40 may assist ingested food to pass from the esophageal extension 20 into the gastric bypass 10 through inlet 12 without significant restriction.

- In addition to holding the inlet 12 of the gastric bypass 10 open, the chamber 40 may also serve to hold the remainder of the gastric bypass 10 open when the chamber 40 is expanded. In some embodiments, the expanded chamber 40 may serve to hold the gastric bypass 10 open to the pyloric region. The expanded chamber 40 may also limit or prevent twisting of the gastric bypass 10. Such limiting or prevention of twisting may be enhanced if the chamber 40 is in the shape of an asymmetric toroid, e.g., the expanded chamber 40 is larger on one side. One potential advantage of such a construction is that twisting or rotation of the chamber 40 itself within the stomach may be limited or prevented.

- Another potential function of chamber 40 is to provide a volume-occupying structure that may tend to induce a feeling of satiation after the patient has consumed a relatively small amount of food.

- The shape of the toroidal chamber 40 may vary from that of a regular toroid, i.e., the exact shaped of the toroidal chamber 40 may be adapted to correspond better to the shape of the stomach. For example, the toroidal chamber 40 may be enlarged on one side to better conform to the shape of the fundus.

FIG. 2 is a cross-sectional view of a portion of a gastric bypass 110 that may be provided in connection with the present invention. The construction of the depicted gastric bypass 110 may, e.g., be used in connection with the gastric bypass depicted and described above in connection with FIG. 1.

5 The gastric bypass 110 may preferably include internal ribs 111 that may serve a number of purposes. For example, the ribs 111 may assist the gastric bypass 110 in maintaining an open internal in the absence of compressive forces thereon. In some embodiments, the ribs 111 may also assist the gastric bypass 110 to resist compression by, e.g., contractions of the stomach. The ribs 111 may extend lengthwise along the
10 gastric bypass 110 (i.e., in direction generally aligned from the esophagus to the pyloric valve). In other embodiments, the ribs 111 may extend helically about the bag 110 or be provided in other configurations.

 Also, although the ribs 111 are depicted as internal to the gastric bypass 110, it should be understood that in some embodiments, the ribs 111 may be located on the
15 external surface of the bag. In other embodiments, ribs may be provided on both the internal surfaces and the external surfaces of the gastric bypass. In still other embodiments, ribs or stiffening structures may be encapsulated within the walls of the of the gastric bypass such that both the interior and the exterior surfaces of the gastric bypass are relatively smooth or flat surfaces.

20 The ribs 111 are depicted as being integral with the structure of the gastric bypass 110. It should, however, be understood that the ribs 111 may alternatively be attached to the bag 110 and may be made of the same or different materials as the gastric bag 110. In some instances, even ribs 111 that are integral with the gastric bypass 110 may be manufactured of materials that are different than the materials used
25 to manufacture the gastric bypass 110 (e.g., through a coextrusion or other molding process).

 FIG. 3 depicts a portion of another gastric bypass 210 with a portion of the gastric bypass 210 cut-away to provide a partial cross-sectional view. The depicted gastric bypass 210 includes one or more sleeves 250, with the sleeves 250 including
30 wires 252 located therein. The sleeves 250 and wires 252 may be provided to assist the gastric bypass 210 in maintaining an open internal volume in the absence of

compressive forces. In addition, the sleeves 250 and wires 252 may assist the gastric bypass 210 in resisting compressive forces.

One potential use of sleeves 250 and wires 252 is that the gastric bypass 210 may be delivered to its deployment site with the gastrointestinal tract without the wires 252 in place within sleeves 250. One potential benefit of such a deployment method is that the gastric bypass 210 may have a lower profile and/or be more flexible to facilitate its deployment. With the gastric bypass 210 in position, the wires 252 may preferably be inserted endoscopically to expand the gastric bypass 210.

Although the sleeves are depicted on the exterior of the gastric bypass 210, it should be understood that they could, alternatively, be located in the interior of the gastric bypass 210. Also the gastric bypass 210 could include one sleeve 250 (and corresponding wire 252) that extends helically about the gastric bypass 210 or a plurality of sleeves 250 and wires 252 could be used. In another variation, one sleeve 250 could be provided with two or more wires inserted therein. In still another variation, a single wire could be inserted into a plurality of sleeves 250 provided on the gastric bypass 210.

Still another variation is that although the sleeves 250 and wires 252 are depicted in a generally helical arrangement relative to the gastric bypass 210, they could be provided in any suitable orientation, e.g., longitudinal (e.g., extending generally from the inlet to the outlet of the gastric bypass 210), annular (e.g., extending about the perimeter of the gastric bypass – in which case it might be preferred to provide a series of the annular sleeves and wires), or any other suitable arrangement (including combinations of different orientations (e.g., annular and longitudinal, etc.).

FIG. 4 depicts another embodiment of a device according to the present invention in which a gastric bypass 310 preferably includes an esophageal extension 320 and a duodenal extension 330 as described in connection with, e.g., the embodiment of FIG. 1. The gastric bypass 310 also includes an expandable chamber 340 attached to an outer surface of the gastric bypass 310, wherein the expandable chamber 340 includes a plurality of adjacent subchambers 350 that may preferably be in fluid communication with each other. The adjacent subchambers 350 may preferably be distributed over at least a portion of the outer surface of the gastric bypass 310 such

that the adjacent subchambers 350 maintain an open volume in the gastric bypass 310 in the absence of compressive forces thereon.

The subchambers 350 may be provided in a geodesic-like pattern as depicted in FIG. 4. Alternatively, the subchambers may take any other suitable shapes, e.g., a series of interconnected annular rings, helical spirals, circles, etc. In some instances, the subchambers may, within the area they are located, cover the entire surface of the gastric bypass 310. In other arrangements, spaces may be provided between the subchambers. The subchambers may also be provided in combinations of two or more different shapes.

In addition to providing expandable subchambers on the gastric bypass itself, it may be advantageous, in some embodiments, to provide one or more expandable chambers and/or subchambers on the duodenal extension to assist it in maintaining patency, i.e., prevent complete closure, twisting, etc.

FIG. 5 is an enlarged cross-sectional view of a portion of the gastric bypass 310 and the associated expandable chamber 340 with its subchambers 350 depicting only one potential construction of the device. The expandable subchambers 350 may be defined by a series of webs 352 extending from the gastric bypass 310, with the webs 352 connected by membrane 354 to form the subchambers 350. The subchambers 350 are preferably in fluid communication with each other. One construction to achieve that fluid communication may include, e.g., openings 356 in one or more webs 352. Some alternative constructions may include webs 352 that are manufactured of permeable materials, etc.

Also, although the expandable chamber 340 is depicted as being located on the external surface of the gastric bypass 310 (with surface 311 being the internal surface of the gastric bypass 310), the expandable chamber 340 and its associated subchambers 350 may alternatively be located on the interior of the gastric bag 310 if so desired. In another variation, it should be understood that more than one expandable chamber 340 may be provided, with each expandable chamber 340 including two or more subchambers 350.

FIG. 6 depicts another exemplary embodiment of a device according to the present invention. The device includes a gastric bypass 410 that preferably includes an

esophageal extension 420 and a duodenal extension 430 as described in connection with, e.g., the embodiment of FIG. 1. The device further includes a chamber 440 that may preferably be expandable to assist in retaining the device in place within the gastrointestinal system as well as to transmit compressive forces from the stomach to the gastric bypass 410 passing therethrough.

A variety of different exemplary embodiments of devices are described above. It should be understood that devices according to the present invention may include one or more of the different features described herein. For example, the gastric bypass 10 of FIG. 1 may include ribs 111 as discussed in connection with FIG. 2. The gastric bypass 10 may, in addition to or in place of ribs, preferably include one or more sleeves 250 and wires 252 as discussed in connection with FIG. 3. Many other combinations of the different features discussed herein may be obtained and used in connection with the present invention and the invention should not be limited to those combinations explicitly discussed herein.

The devices of the present invention may preferably be adapted for delivery into the gastrointestinal system endoscopically, although other placement techniques and methods may also be possible. A variety of different delivery methods and structures may be described in, e.g., U.S. Patent Nos. 4,315,509 (Smit); 4,501,264 (Rockey); and 5,306,300 (Berry); as well as U.S. Patent Publication No. US 2003/0040804 A1 (Stack et al.).

The devices of the present invention may be manufactured of a variety of materials, although the materials used in the devices may preferably be compatible with long-term exposure to ingested food, gastrointestinal fluids (e.g., low pH stomach fluids and high pH intestinal fluids), mechanical stresses associated with the gastrointestinal system, etc. Examples of some suitable materials for the gastric bypass, expandable chambers, esophageal extensions, duodenal extensions, etc. may include, but are not limited to, polymeric materials (e.g., silicone elastomers, polyethylenes, polyether polyurethanes (e.g., TEGADERM), polytetrafluoroethylenes (PTFE), and other materials. If metallic materials such as wires, struts, meshes, etc. are incorporated into the devices of the present invention, they may include, e.g., shape memory metals (such as nickel-titanium alloys), stainless steel, etc. In some instances, the devices of the

present invention may include shape memory polymers for one or more different components such as the expandable chambers, etc.

The expandable chambers of the different devices according to the present invention may expand due to mechanical forces associated with wires or other structural members made of stainless steel, shape memory metals, shape memory polymers, etc.
5 In other embodiments, the expandable chambers may be expanded by inflation with a fluid, e.g., saline, air, etc. If a liquid is used for inflation, it may desirably include a dye to provide the patient with an indication that one or more of the chambers has ruptured or is otherwise leaking.

10 In still other embodiments, the expansion may be provided by gel or polymer-based structural material (e.g., foam, etc.) that, as delivered, is uncured but is expanded/cured when the device is in place in the gastrointestinal system. For example, with the device in location within a patient, the expandable chamber could be expanded and then filled with a solution containing a non-toxic activating agent to expand and fix
15 the structural material. The expanded material within the expandable chamber would preferably provide structural rigidity to resist collapse and preferably also induce satiation. In some embodiments, the expanded material may preferably be biodegradable and/or bioresorbable such that it could slowly erode over time to assist in, e.g., endoscopic removal of the device.

20 One potentially suitable expandable structural material may be a polylactic acid polymer (PLA, e.g., poly-DL-lactide, etc.) which may be provided as a liquid when dissolved in a solvent such as NMP (N-methyl-2-pyrrolidone), but hardens into a pliable structural material when the NMP diffuses out of the polymer mixture. Both NMP and the polymer PLA are generally considered to be inert and bioresorbable for
25 use within the human (or animal) body. Other expandable structural materials may be known to those skilled in the art.

As used herein and in the appended claims, the singular forms "a," "and," and "the" include plural referents unless explicitly limited to the singular form or the context
30 clearly dictates otherwise.

All references and publications cited herein are expressly incorporated herein by reference in their entirety into this disclosure. Illustrative embodiments of this invention are discussed and reference has been made to possible variations within the scope of this invention. These and other variations and modifications in the invention
5 will be apparent to those skilled in the art without departing from the scope of the invention, and it should be understood that this invention is not limited to the illustrative embodiments set forth herein. Accordingly, the invention is to be limited only by the claims provided below and equivalents thereof.

CLAIMS:

1. An implantable gastro-intestinal device comprising:
a gastric bypass comprising an inlet and an outlet;
5 an expandable chamber attached to the gastric bypass;
an esophageal extension attached to the inlet of the gastric bypass, wherein food
passes into the gastric bypass through the esophageal extension;
a duodenal extension attached to the outlet of the gastric bypass, wherein the
duodenal extension receives material exiting the outlet of the gastric bypass.
10
2. A device according to claim 1, wherein the gastric bypass comprises a flaccid
gastric bag.
3. A device according to claim 1, wherein the gastric bypass comprises ribbing
15 molded therein, wherein the ribbing maintains an open volume in the gastric bypass in
the absence of compressive forces thereon.
4. A device according to claim 1, wherein the gastric bypass comprises a sleeve
containing a wire, wherein the sleeve and wire cooperate to maintain an open volume in
20 the gastric bypass in the absence of compressive forces thereon.
5. An implantable gastrointestinal device comprising:
a gastric bypass comprising an inlet and an outlet;
an expandable chamber attached to an outer surface of the gastric bypass,
25 wherein the expandable chamber comprises a plurality of adjacent subchambers in fluid
communication with each other, wherein the plurality of adjacent subchambers are
distributed over at least a portion of the outer surface of the gastric bypass, and wherein
the plurality of adjacent subchambers maintain an open volume in the gastric bypass in
the absence of compressive forces thereon;
30 an esophageal extension attached to the inlet of the gastric bypass, wherein food
passes into the gastric bypass through the esophageal extension;

a duodenal extension attached to the outlet of the gastric bypass, wherein the duodenal extension receives material exiting the outlet of the gastric bypass.

6. A device according to claim 5, wherein the plurality of adjacent subchambers
5 are arranged in a quasi-geodesic pattern.

7. An implantable gastro-intestinal device comprising:
a gastric bypass comprising an inlet and an outlet;
an expandable toroidal chamber located proximate the inlet of the gastric
10 bypass, wherein the toroidal chamber holds the inlet in an open configuration when the toroidal chamber is inflated;

an esophageal extension attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension;

- a duodenal extension attached to the outlet of the gastric bypass, wherein the
15 duodenal extension receives material exiting the outlet of the gastric bypass.

8. A device according to claim 7, wherein the gastric bypass is flaccid outside of the toroidal chamber.

- 20 9. A device according to claim 7, wherein the toroidal chamber is asymmetric.

CERTIFICATE UNDER 37 CFR §1.10:

"Express Mail" mailing label number: **EV 405458496 US**

Date of Deposit: **FEBRUARY 25, 2004**

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By: Sam Cl

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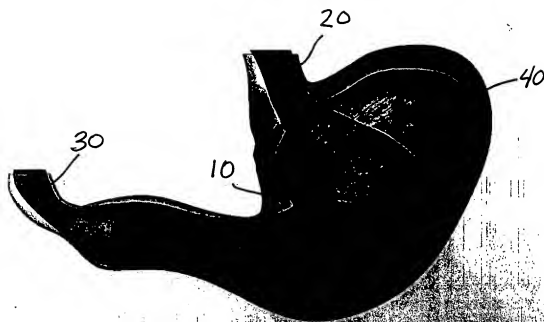


FIG. 1A

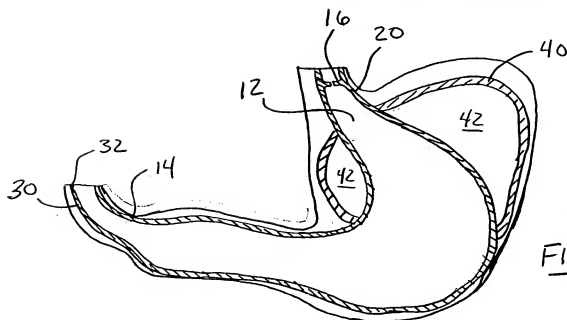
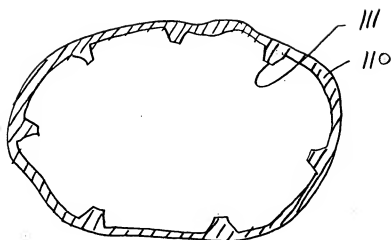
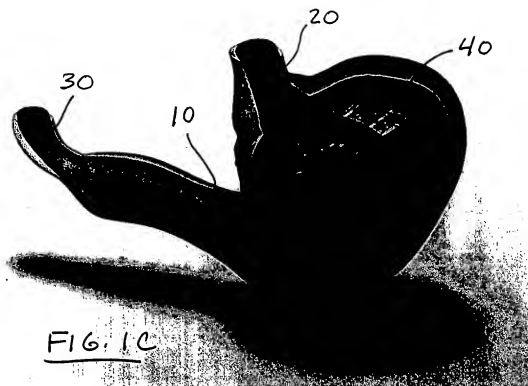


FIG. 1B



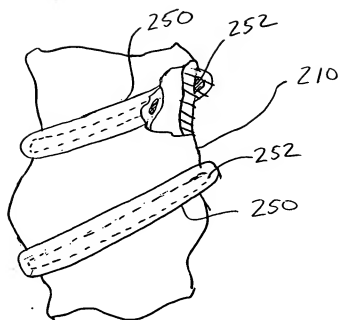


FIG. 3

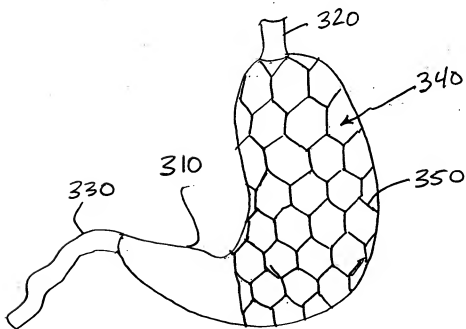


FIG. 4

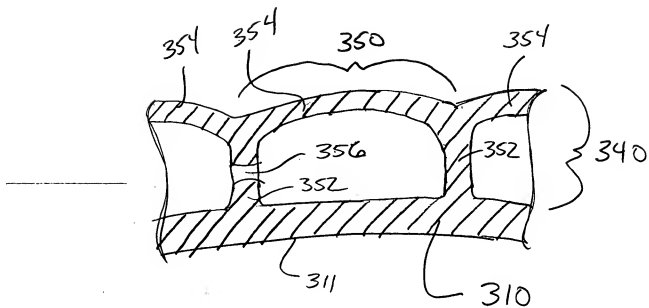


FIG. 5

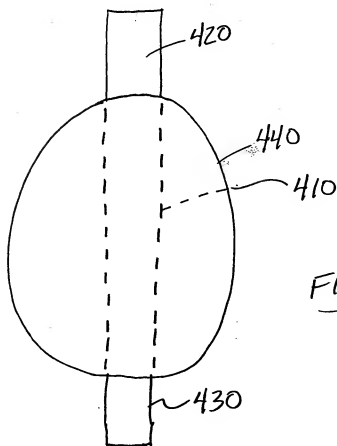


FIG. 6

APPLICATION DATA SHEET

APPLICATION INFORMATION

Application Type::	PROVISIONAL
Subject Matter::	UTILITY
CD-ROM or CD-R?::	NONE
Title::	GASTRIC BYPASS DEVICES AND METHODS
Attorney Docket Number::	230.00090160
Total Drawing Sheets::	4

INVENTOR INFORMATION

Applicant Authority Type::	INVENTOR
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City of Mailing Address::	Rochester
State or Province of Mailing Address::	MN
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	55901

Applicant Authority Type::	INVENTOR
Primary Citizenship Country::	US
Status::	FULL CAPACITY
Given Name::	Christopher
Middle Name::	J
Family Name::	GOSTOUT
City of Residence::	Rochester
State or Province of Residence::	MN
Country of Residence::	US
Street of Mailing Address::	182 Evergreen Drive NE
City of Mailing Address::	Rochester
State or Province of Mailing Address::	MN

Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 55906

Applicant Authority Type:: INVENTOR
Primary Citizenship Country:: US
Status:: FULL CAPACITY
Given Name:: Kevin
Middle Name:: E
Family Name:: BENNET
City of Residence:: Rochester
State or Province of Residence:: MN
Country of Residence:: US
Street of Mailing Address:: 819 4th St SW
City of Mailing Address:: Rochester
State or Province of Mailing Address:: MN
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 55902

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 26813

REPRESENTATIVE INFORMATION

Representative Customer Number:: 26813